MICROBIAL AIR SAMPLER

BACKGROUND OF THE INVENTION

Field of the Invention

[0001] The present invention relates to a microbiological gas sampler, and especially for sampling air. More particularly, the present invention relates to a microbial air sampler used in a controlled environment.

Background of the Related Art

[0002] A controlled environment is an area which is designed, maintained, or controlled to prevent particle and microbiological contamination of products. Controlled environments include, for example, clean rooms and clean hoods. There are different levels of cleanliness in clean rooms, generally in the range of a Class 100 room (*i.e.*, a room having no more than 100 particles of 0.5 micron and larger, per cubic foot of air (0.01766 mm and larger, per cubic meter), to a Class 10,000 clean room.

[0003] Clean rooms are used for a variety of purposes, such as in the manufacture of pharmaceutical products and electronics, such as semiconductors. Often, clean rooms are used to work on extremely expensive and complex products, and it is not unusual that there be millions of dollars worth of product in a clean room at any given time. Clean rooms have to maintain a high level of cleanliness, or risk large financial losses. If a product being developed or manufactured in a clean room becomes contaminated, the entire product in the clean room must often be discarded.

[0004] Microbial air samplers are used to monitor the level of cleanliness (in terms of viable contamination) in a controlled environment. One or more samplers are positioned about the

clean room to collect airborne particulates and organisms (or microorganisms) such as bacteria and fungi. Samplers that run at high flow rates permit air to enter the sampler at such high flow

rates that loss of smaller particulates carrying microorganisms is normality (*i.e.*, smaller particulates are not retained in the medium). At the same time high flow rate air samplers only sample for a short time period and relay on a short snapshot of the condition of the area. Samplers running at 28.3 LPM (liters per minute) (0.472 liters per second) must operate for a longer period of time than a unit running at 322 LPM (5.37 liters per second). In doing this, they sample a broader spectrum of the drug fill time and present superior data as the sample time takes a larger snapshot of the operation. Samplers that run at 28.3 LPM (0.472 liters per second) also provide the ability to capture more smaller particulates that may be lost due to dynamic drag (or an umbrella affect) in higher flow rate units.

[0005] Air sampling systems are generally known, and an air sampling system is offered by Veltek Associates, Inc. known as SMA (Sterilizable Microbiological Atrium) Microbial Air Sampler System. One such system is shown in U.S. Patent Application Nos. 12/068,483, filed Feb. 7, 2008 and 12/402,738, filed March 12, 2009, and the counterpart PCT published application WO2009/100184,. As noted in those applications, the air sampler system includes a controller connected to a vacuum pump to control the flow of air to air sampler devices located in the clean room.

[0006] A prior art air sampler device 5 is shown in Figs. 1-2, which is offered by Veltek Associates, Inc. The air sampler device 5 includes a top plate 10 with openings 11 and a bottom plate 14. The bottom plate 14 has a circular ridge 16 on the top surface, which receives a Petri dish 12. The underside of the bottom plate 14 has a circular channel 20 (best shown in Fig. 2) which communicates with an air port 22. A metal cover plate 26 fits over the underside of the bottom plate 14, and a rubber gasket 24 is positioned between the bottom plate 14 and the cover

plate 26 to provide an airtight seal. Screws are used to secure the cover plate 26 and gasket 24 to the bottom plate 14. In addition, a circular rubber gasket (not shown, but having the shape of a

washer) is positioned on the top surface of the bottom plate 14 around the circular ridge 16 to create a substantially airtight seal between the bottom plate 14 and the top plate 10.

[0007] In operation, a vacuum tube is attached to the air port 22. Air is then sucked in through the openings 11 located in the top plate 10, so that the air strikes a test medium contained in the Petri dish 12. The air then exits the device 5 through holes 18 located on the ridge 16 of the bottom plate 14. The air passes into the channel 20, and exits through the air port 22. The entire device 5 is metal, except for the gasket 24, so that the device 5 can be sterilized by heat, steam, Vaporized Hydrogen Peroxide (VHP) or Ethylene Oxide (ETO). At the end of the testing period, the Petri dish 12 is removed and analyzed to determine the level of cleanliness of the clean room.

[0008] The Petri dish 12 has a diameter of about 3.5 inches (88.9mm). The top plate 10 has a diameter of 4.5 inches (114.3mm). There are twelve holes 11 positioned within about a circular area having a 3 inch (76.2mm) diameter, and each hole 11 has a diameter of about 0.5 inches (12.7mm). The sides of the top plate 10 and the bottom plate 14 are smooth.

SUMMARY OF THE INVENTION

[0009] Accordingly, ~~it is an object~~embodiments of the invention seek to provide a device for sampling viable cells in air. ~~It is another object~~An embodiment of the invention seeks to provide a microbial air sampler having an improved design which is entirely sterilizable by heat, steam, VHP or Ethylene Oxide (ETO) and does not include a gasket. ~~It is yet another object~~Another embodiment of the invention seeks to provide a microbial air sampler which can accommodate current Petri dish shapes and sizes.

[0010] Accordingly, an air sampler device is provided having a top plate having a vent plate with a plurality of at least 100 holes, each hole having a diameter of less than 0.01 inches, and the plurality of holes comprising less than 0.5% of the vent plate; a bottom plate having a top surface and a receiving portion at the top surface for receiving a dish, the top plate and the bottom plate forming an enclosure; a center well formed in the top surface of said bottom plate; a plurality of elongated slots formed in the top surface of said bottom plate, said plurality of elongated slots extending outward from said center well beyond the receiving portion; a ridge projecting upward from the top surface of said bottom plate, said ridge defining the receiving portion; and an air port configured to draw gas into the enclosure through the plurality of holes in said top plate to impinge on the dish, wherein the plurality of elongated slots extend into said ridge. ~~a~~The top plate and ~~a~~the bottom plate, ~~which~~ receives a Petri dish between the top plate and the bottom plate. In an embodiment, ~~T~~the top plate includes 283 substantially small holes. The bottom plate has a deepened center well formed in the top surface at the center of the bottom plate. ~~Six~~In an embodiment, six elongated slots are formed in the top surface with proximal ends which extend out from the central well, and distal ends which extend beyond the Petri dish situated about the

center of the bottom plate. In one aspect of the invention, a gas sampler is provided, comprising a top plate having a vent plate with a plurality of at least 100 holes, each hole having a diameter of less than 0.01 inches, and the plurality of holes comprising less than 0.5% of the vent plate; a bottom plate having a top surface and a ridge projecting upward from the top surface, said ridge defining a receiving portion for receiving a dish; a center well formed in the top surface of said bottom plate; a plurality of elongated slots formed in the top surface of said bottom plate and extending outward from said center well, each of said plurality of elongated slots having a proximal end in flow communication with said center well and a distal end in the ridge beyond the receiving portion; a gas passageway formed in said bottom plate, said gas passageway in flow communication with said center well and extending through said bottom plate to outside said bottom plate; and an air port located outside the bottom plate and in flow communication with said gas passageway, said air port connecting to a vacuum tube and configured to draw gas into said device through said top plate to impinge on the dish and travel through said plurality of elongated slots into said well.

[0011] In operation, air is drawn into the sampler device by a vacuum tube through an air port which communicates with the center well. Air is pulled into the 283 holes in the top plate and strikes the capture material in the Petri dish. The air then travels up over the sides of the dish and into the distal ends of the slots of the bottom plate. The air then travels down the elongated slots beneath the dish, and enters the center well. The air is then sucked through the air passageway hole and exits out of the vacuum air port.

[0012] These and other objects of the invention, as well as many of the intended advantages thereof, will become more readily apparent when reference is made to the following description, taken in conjunction with the accompanying drawings.

substantially airtight, without the need of a gasket to seal any metal-on-metal contact points. The entire device 50 can be sterilized by heat, steam, VHP or ETO.

[0032] Furthermore, because the holes 112 in the top plate 100 are small, the elongated slots 156 and distal ends 159 can be made larger while retaining a high air flow rate through the holes 112. By having larger slots 156, distal ends 159, center well 158 and hole 162, the device 50 is less susceptible to becoming clogged. Though six slots 156 are provided in the illustrated embodiment, fewer or more slots can be provided, though preferably the slots are equally spaced about the Petri dish so that the distal ends uniformly draw air from the dish.

[0033] In accordance with the preferred embodiment of the invention, the vent plate 110 has a diameter of approximately 2.5 inches (63.5mm) and a thickness of 0.0600 inches (1.524mm). The size (i.e., diameter) of the vent plate 110 is substantially smaller than the size (i.e. diameter) of the Petri dish 52, to reduce the desiccation or drying of the edges of the nutrient media. The preferred ratio is about 3:4 (*i.e.*, 2.5 inch (63.5mm) diameter for the vent plate 110 to a 3.25 inch (82.55mm) diameter for the Petri dish), or that the vent plate is no larger than about 75% of the size of the Petri dish. A larger ratio creates results in an air speed which adversely affects an uneven part of the media plate since the media plate is poured agar (nutrient media), which sometimes moves up the sides of the Petri dish 52 which becomes dried.

[0034] Each hole 112 has a diameter of about 0.0070 inches (0.1778 mm), which is approximately 0.00078% of the size of the vent plate. Since there are 283 holes over the 2.5 inch (63.5mm) diameter plate 110, the holes 112 account for approximately 0.22% of the area of the vent plate 110. The holes 112 are positioned in 9 concentric rings at the following diameters: 0.0 (1 hole), 0.40625 (10 holes), 0.65625 (15 holes), 0.90625 (20 holes), 1.15625 (26 holes), 1.40625 (31 holes), 1.65625 (37 holes), 1.90625 (42 holes), 2.15625 (48 holes), and 2.40625 (53 holes). It

should be appreciated, however, that the size of the holes 112 can vary within the spirit of the invention, and the number of holes 112 may be more or less than 283. Preferably, however, there are at least 100-150 holes, and more preferably at least 200 holes, with each hole being less than 0.01 inches (0.254mm) and preferably 0.007-0.009 inches (0.1778mm-0.2286mm) in diameter. Preferably, however, the holes 112 comprise less than about 1%, of the surface area of the vent plate 110 (*i.e.*, the area in which the holes are located).

[0035] By having small holes 112 in the top plate 100, air is drawn into the sampler 50 at a high flow rate (about 67.20 m/s per hole) and volume (about 1.67E-06 m^3/s per hole), while keeping the flow rate at 1 CFM (or 28.3 cubic liters per minute (0.472 cubic liters per second)) at the air port 160 to provide a longer sampling time. The flow rate of the air as it is drawn into the holes 112 is about 28.3 LPM (0.472 cubic liters per second)or 1 CFM (0.00472 cubic meters per second)or through each hole 0.1 is LPM. The total for the top plate 100 is about 0.000472 m^3/s. Particle sizes of about 0.2-9 microns may be reflected, while 10+ microns are deposited. Particles of 0.2-9.0 microns (0.0002mm to 0.009mm) can be swept away from dynamic drag if the airflow is too high, so that airflow is reduced to capture those smaller particulates. The sampler 50 has an efficiency loss of about 5.6-7.2%, which is much lower than conventional samplers which have an average loss of approximately 20%.

The faster air flow at the holes 112 provides higher capture realization in the material located in the Petri dish 52 since the particles can't bounce off of the capture material. The sampler 50 will capture particles which are approximately 0.5-30 μm in size. The well 158 is one inch in diameter, and about 3/8 inches (9.525mm) deep from the top surface 152. The slots 156 are about 0.25 inches (6.35mm) wide and the distal end 159 of the slots 156 extends 1/8 inch (3.175mm) into the ridge 154. The ridge 154 is 0.25 inches (6.35mm) wide. Though six slots

156 are provided, more or fewer slots can also be utilized. The sampler 50 can be utilized with the sampling system shown in WO2009/100184. The capture material in the Petri dish 52 is usually a bacterial growth

medium, such as trypticase soy agar, though any suitable medium can be used. The dish 52 has a diameter of 3.5 inches (88.9mm) and can retain 18, 25 or 32 ml of capture material, though the dish 52 can be any suitable size.

[0036] Further to the preferred embodiment, the top plate 100 and the bottom plate are both circular, with a diameter of approximately 4.5 inches (114.3mm). The completely assembled sampler device 50 is shown in Figure 7. The bottom plate 150 is sized and shaped substantially the same as the top plate 100, though the top plate 100 can be slightly larger to further assist in removing it from the bottom plate 150 without disturbing the bottom plate 150. Though the device 50 is shown as circular, other shapes may be used. And, the device 50 may be substantially larger or smaller than the dimensions provided.

[0037] The plates 100, 150 are preferably made of stainless, anodized aluminum. The bottom of the sides 114 of the top plate 100, and the top shelf 153 of the bottom plate 150, are machined to a sufficient degree to provide a substantially airtight seal therebetween without the need for a gasket or other element. The plates 100, 150 are relatively heavy, so that they do not break, get knocked over, and creates a relatively airtight seal between the plates. There is approximately 0.015 inches (0.381mm) between the outer portion of the ridge 154 and the side wall 114 of the top plate 100. In addition, a metal cover can be provided which covers the top plate 100. The cover is larger than the top plate 100, preferably with a diameter of 4 5/8 inches (117.475mm), so that it can be easily removed from the top plate 100. The cover prevents particles from entering the device 50 when it is not being operated.

[0038] The foregoing description and drawings should be considered as illustrative only of the principles of the invention. The invention may be configured in a variety of shapes and sizes and is not intended to be limited by the preferred embodiment. Numerous applications of the

8. The gas sampler device of claim 1, wherein each hole has a diameter of less than 0.009 inches (0.2286mm).

9. The gas sampler device of claim 1, wherein each hole has a diameter of approximately 0.007 inches.

10. The gas sampler device of claim 1, wherein the gas sampler device is configured such that gas may be drawn into the plurality of holes at a speed of approximately 67.20 m/s per hole when the volume of gas entering the plurality of holes is approximately 1.6E-06 m^3/s per hole.

11. A gas sampler device comprising:

a top plate having a vent plate with a plurality of at least 100 holes, each hole having a diameter of less than 0.01 inches, and the plurality of holes comprising less than 0.5% of the vent plate;

a bottom plate having a top surface and a ridge projecting upward from the top surface, said ridge defining a receiving portion for receiving a dish;

a center well formed in the top surface of said bottom plate;

a plurality of elongated slots formed in the top surface of said bottom plate and extending outward from said center well, each of said plurality of elongated slots having a proximal end in flow communication with said center well and a distal end in the ridge beyond the receiving portion;

a gas passageway formed in said bottom plate, said gas passageway in flow communication with said center well and extending through said bottom plate to outside said bottom plate; and

an air port located outside the bottom plate and in flow communication with said gas passageway, said air port connecting to a vacuum tube and configured to draw gas into said device through said top plate to impinge on the dish and travel through said plurality of elongated slots into said well.

12. The gas sampler device of claim 11, said top plate having a top surface with a depressed portion, wherein the plurality of holes are provided in the depressed portion.

13. The gas sampler device of claim 11, wherein the plurality of holes comprise over 100 holes.

14. The gas sampler device of claim 11, wherein the plurality of holes each have a diameter of approximately 0.0070 inches (0.1778mm).