Development of the Industry's Fastest Cell Culture CO_2 Incubator Decontamination Process Using Hydrogen Peroxide Vapor (H_2O_2)

In 2018, PHC tested the following MCO-170AICUVH-PE, MCO-230AICUV-PE with optional H_2O_2 decontamination system. Cell culture CO_2 incubators with H_2O_2 vapor decontamination.

NOTE

1. This validation of the use of hydrogen peroxide vapor for decontamination specifically relates to the decontamination of the CO_2 Incubators. It does not invalidate the specific use of high temperature sterilization protocols for other PHCbi incubators.
2. All of the H_2O_2 cycles (and other testing) performed in the "-PE" models perform equivalently to the "-PA" and "-PK" models.

Abstract

The value of the laboratory cell culture incubator used in highly regulated research and clinical protocols is directly related to the proportion of incubator uptime vs. downtime in applications where frequent interior chamber decontamination is required or desired. The need for interior decontamination before initiating new applications for *in vitro* fertilization*, stem cell research and regenerative tissue culture is more frequent than longer-term cell culture work. The return on investment favors short, labor-saving decontamination cycles with validation of the decontamination process for GMP applications. The use of a hydrogen peroxide vapor (H_2O_2) generator *in situ* to decontaminate the cell culture CO_2 incubator without the use of heat decontamination offers significant advantages in routine clinical and highly regulated research laboratories where costly downtime must be avoided. The combination of a seven-minute H_2O_2 vapor in the chamber, circulated by the incubator airflow fan, followed by exposure to narrow band width ultraviolet light establishes a thorough antimicrobial impact on all incubator walls, shelves, reservoirs, air plenums, sensors and other interior components This H_2O_2 decontamination is achieved without the time and expense of high heat cycles, leaving only small amounts of water droplets as a residual.

Test Protocol and Results

- *Objective:* To certify effective decontamination of the inner chamber of an incubator by hydrogen peroxide gas.
- *Product Identification:* CO_2 incubator MCO-170AICUVH-PE, MCO-230AICUV-PE with optional H_2O_2 decontamination system.
- *Test Microorganism: Geobacillus stearothermophilus* ATCC 12980 (spore) selected by PHC. This microorganism is used as an index microorganism in verification of H_2O_2 vapor technologies for decontaminating indoor surfaces contaminated with biological or chemical agents issued by the United States Environmental Protection Agency. Biological Indicator (BI) for H_2O_2 gas from *Apex Laboratories, Inc., Lot Batch No. H0038*.
- *Test Method: The test method was conducted according* to decontamination effect validation protocol that is attached to the product. Following the protocol, biological indicators were positioned at strategic locations in the inner chamber of the incubator. The inner chamber was decontaminated using the product H_2O_2 decontamination mode. After decontamination, biological indicators were put into Tryptic Soy Broth (BBL) and cultured at 55°C for one week. Location map detailed in report. Test results are available from PHC on request.
- *Test Result:* No growth was exhibited in any of the biological indicators the decontamination of the inner chamber by hydrogen peroxide gas was certified See Table 1.

Table 1

BIOLOGICAL INDICATOR	TEST 1	TEST 2	TEST 3
INTERIOR	-	-	-
CONTROL	+	+	+

Table 1: Biological Indicator Culture Results, H_2O_2 Decontamination with UV Cycle, Biological Indicator (BI) *Geobacillus stearothermophilus* ATCC 12908 (spore), by Apex Laboratories, Inc., H0038 Confidential Test Report no. 17/049, April 17, 2018

For USA:
* IVF applications only for MCO-170M-PA
MCO-170AICL-PA / MCO-170AICUVL-PA / MCO-230AICL-PA / MCO-230AICUVL-PA are for laboratory use.

For EU:
MCO-170AIC-PE / MCO-170AICUV-PE / MCO-170AICUVH-PE / MCO-230AIC-PE / MCO-230AICUV-PE series are certified as a Class IIa Medical Device (93/42/EEC and 2007/47/EC) for medical purposes of culturing cells, tissues, organs and embryos.

PHC Corporation

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